March 14, 2019

Abbott Laboratories
Linda Morris
1921 Hurd Drive
Irving, Texas 75038

Re: k060574
Trade/Device Name: Total Bilirubin
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG, MQM, JIT
Dated: March 3, 2006
Received: March 6, 2006

Dear Linda Morris:

This letter corrects our substantially equivalent letter of May 3, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060574

Device Name: Total Bilirubin

Indications For Use:

The Total Bilirubin assay is used for the quantitation of total bilirubin in human serum or plasma. Measurement of total bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

Prescription Use ✓ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Carol C Benson

510(k) K060574

MAY 3 2006

510(k) Summary

Submitter's Name/Address
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Date of Preparation of this Summary:	March 3, 2006
Device Trade or Proprietary Name:	Total Bilirubin
Device Common/Usual Name or Classification Name:	Total Bilirubin Reagent
Classification Number/Class:	CIG/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K060574

Test Description:

Total Bilirubin is an in vitro diagnostic assay for the quantitative determination of total bilirubin in human serum or plasma of adults and neonates. Total (conjugated and unconjugated) bilirubin couples with the diazo reagent in the presence of a surfactant to form azobilirubin. The increase in absorbance at 548 nm due to azobilirubin formation is directly proportional to the total bilirubin concentration.

Substantial Equivalence:

The Total Bilirubin assay is substantially equivalent to the Roche Total Bilirubin assay (K910591) on the Hitachi 717 Analyzer. These assays yield substantially equivalent Performance Characteristics.

Similarities:

- Both assays are in vitro colorimetric chemical reactions.
- Both assays can be used for the quantitative analysis of total bilirubin in human serum or plasma of adults and neonates.
- Both assays yield similar results.

Differences:

None

Intended Use:

The Total Bilirubin assay is used for the quantitative analysis of total bilirubin in human serum or plasma of adults and neonates.

Performance Characteristics:

Adult Application: Correlation data are presented in Tables 1 and 3, and Figures 1 through 3. One hundred thirty-seven adult serum samples ranging from 0.21 to 24.41 mg/dL (based on the Roche Total Bilirubin assay on the Hitachi 717 Analyzer assay results) showed a correlation coefficient of 0.9992, slope of 0.96, and Y-intercept of 0.22 mg/dL using the AEROSET System. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9992, slope of 0.95, and Y-intercept of 0.20 mg/dL when compared to the Hitachi 717 Analyzer. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9999, slope of 0.99 and Y-intercept of –0.02 mg/dL when compared to the AEROSET System. The Total Bilirubin assay method comparison yielded acceptable correlation between the AEROSET System and ARCHITECT *c*8000 System.

Neonate Application: Correlation data are presented in Tables 2 and 4, and Figures 4 through 6. Fifty-two neonate serum samples ranging from 4.65 to 15.9 mg/dL (based on the Roche Total Bilirubin assay on the Hitachi 717 Analyzer assay results) showed a correlation coefficient of 0.9934, slope of 0.96, and Y-intercept of 0.22 mg/dL using the AEROSET System. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9921, slope of 0.98, and Y-intercept of 0.06 mg/dL when compared to the Hitachi 717 Analyzer. The ARCHITECT *c*8000 System showed a correlation coefficient of 0.9964, slope of 1.02 and Y-intercept of –0.13 mg/dL when compared to the AEROSET System.

Precision studies were conducted using the Total Bilirubin assay. On the AEROSET System, the total %CV for Level 1 is 1.33%, Level 2 is 1.56%, Level 3 is 1.32%, and Level 4 is 0.9%. On the ARCHITECT *c*8000 System, the total %CV for Level 1 is 1.68%, Level 2 is 2.13%, Level 3 is 1.84%, and Level 4 is 1.3%. The Total Bilirubin assay is linear from 0.1 to 25 mg/dL. The functional sensitivity (limit of quantitation) of the Total Bilirubin assay is $\leq$ 0.1 mg/dL and the limit of detection (LOD) 0.05 mg/dL.

These data demonstrate the performance of the Total Bilirubin assay is substantially equivalent to the performance of the Roche Total Bilirubin on the Hitachi 717 Analyzer.

Conclusion:

The Total Bilirubin assay is substantially equivalent to the Roche Total Bilirubin assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.